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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

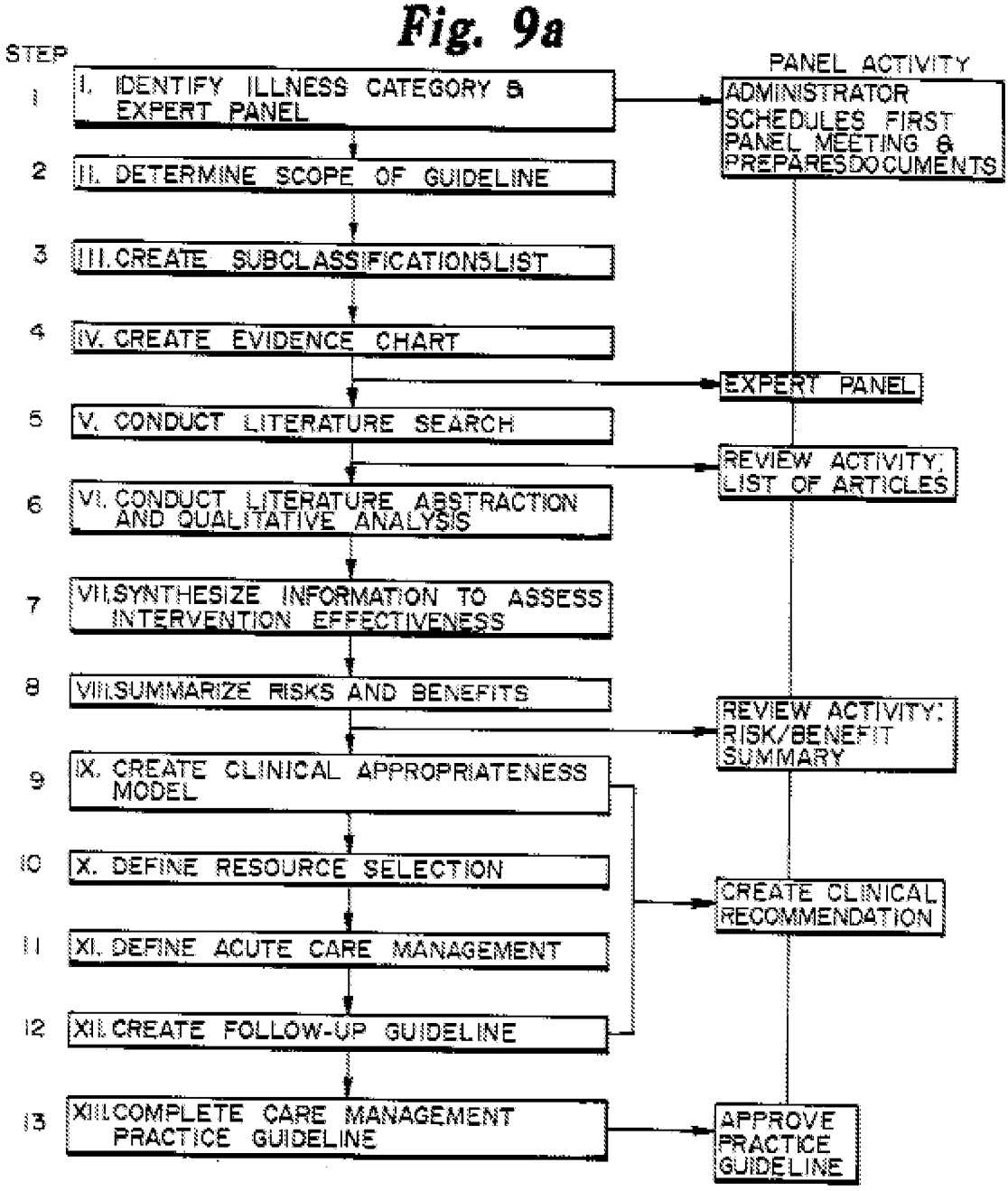
ADVISORY ACTION

Response to Arguments

Applicant's arguments filed 01/26/2010 have been fully considered but they are not persuasive.

On page 3-4 Applicant appears to be arguing that the applied art do not teach using key characteristics of a plurality of patients to develop logical rules for analysis, and then applying those rules to a particular patient.

McIlroy teaches:



In particular, McIlroy teaches (column 8-10):

The content of a guideline requires that it reflect accepted clinical practice when formulated and also requires: (a) ongoing evaluation to ensure appropriateness; and (b) assessment of its implementation to ensure consistent application and appropriate sensitivity and specificity of its contents. The clinical content of each guideline needs to be based on available evidence and refined by result of application. Thus, guidelines are developed first as diagnosis and treatment models by health care professionals and these models are refined to sufficient definiteness to permit their coding.

FIG. 9*a* is a chart outlining the guideline development process. At step 1 the illness category that the guideline will cover is identified. This decision is usually based on existing patterns, such as the volume of cases for an illness category, the extent of variations in treating an illness, or cost for treating an illness. A panel of people with expertise in the selected illness category or in research procedures is established.

At step 2, the scope, i.e., components of care, of the guideline is identified. The four major components that a guideline may include are diagnostic guideline, therapeutic

selection, resource selection, and acute care management. The care components decision is based on the purposes for developing the guideline, understanding how it would be implemented, and the financial resources available for guideline development.

At step **3**, any subclassifications used to identify severity levels of the illness with a set of treatment options are identified. The subclassifications should be standard groupings whenever possible, so they will be consistent with data used in future analyses.

At step **4**, an evidence chart that defines aspects of the diagnosis or treatment which require specific scientific support or evidence is developed. This evidence is necessary to determine the impact on expected clinical outcomes of a specific intervention. It also describes potential adverse affects or outcomes and complications which will need to be considered in evaluating overall risks and benefits.

At step **5**, a literature search is conducted. Prior to conducting the literature search it is important to define the search logic, process, and list of exclusions in order to efficiently expend time and resources. The evidence chart helps organize the information to complete the literature search.

At step **6**, evidence retrieved for each linkage of the evidence chart is documented in a standard format. The data abstraction process is completed. The results are summarized to specifically document the results of each study.

At step **7**, quantitative analysis is used to draw conclusions about a particular intervention's effectiveness. Narrative summaries are created of the information for each intervention, describing the impact on expected outcome. This synthesis of information, including the narrative summary, is provided to knowledge experts for a decision of clinical impact of intervention on expected outcome.

At step **8**, a summary of the risks and benefits of interventions appropriate to a diagnosis is generated. This summary may include positive outcome, grade of impact, contraindication, adverse affect/mortality, adverse affect/morbidity, disability, discomfort and cost impact. At this point a meeting of the expert panel occurs. During this meeting the risk summary benefit is reviewed, resource selection, key management and follow-up guidelines are defined, and consensus on the guideline is reached.

At step **9**, a clinical appropriateness model is created by the panel that describes by intervention: patient characteristics for which the intervention is indicated and contraindications, with appropriate alternative when present. This information is then aggregated into a guideline.

At step **10**, for each intervention adopted into the guideline, the panel determines a minimum level of resource required to administer the treatment. This includes evaluating the setting, assistant surgeon requirement and potential variables affecting resources.

At step **11**, acute care management is defined. For each intervention requiring an inpatient stay, the panel determines the appropriate length of stay including preoperative days.

At step **12**, following completion of a guideline, the panel develops guidelines for extended care, which include the indications, treatments and related resources.

At step **13**, the panel reviews the entire guideline for clarity and accuracy. Panel members vote formally for adoption of each guideline.

Guidelines are continuously updated by recurring searches by diagnosis for new findings and studies. Also each guideline can be reviewed on a periodic basis, such as

annually. Information from the care management system can be retrieved for that review, including results of use, frequency of use, frequency of variation by component, type of variations. Because the present invention implements the guidelines as data base parameters, the system is flexible; it can be readily adapted to changes in and evolution of health care professional knowledge and treatment methods.

According to McIlroy, these guidelines are developed based on evidence obtained from a plurality of patients. McIlroy further teaches refining these guidelines based on clinical evidence as the direct results from the application of these guidelines.

Conclusion

In view of the totality of the evidence, the finality of the previous Office Action is hereby maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gerald (Jerry) J O'Connor can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
02/04/2010

/Robert Morgan/
Primary Examiner, Art Unit 3626